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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0269; FRL-9905-80]

Cyflumetofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyflumetofen in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0269, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0269 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0269, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2012 (77 FR 30481) (FRL-9347-8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F7973) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cyflumetofen (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), in or on almond, hulls at 4.0 parts per million (ppm); citrus, oil at 16 ppm; fruit, citrus, group 10 at 0.3 ppm; fruit, pome, group 11 at 0.3 ppm; grape at 0.6 ppm; grape, raisin at 0.9 ppm; nut, tree, group 14 at 0.01 ppm; strawberry at 0.6 ppm; and tomato at 0.2 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA modified some of the tolerance levels and commodity names requested by the applicant. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and

children. The major target organ in rats, mice, and dogs following short-term and long-term oral administration of cyflumetofen is the adrenal glands characterized by increased organ weight and histopathology (vacuolation and hypertrophy of the adrenal cortical cells).

Cyflumetofen has low acute toxicity by oral, dermal, and inhalation routes of exposure. It is minimally irritating to the eyes but not to the skin. It is a skin sensitizer.

Decreased serum hormone concentrations (FSH, progesterone, and 17 β-estradiol) were observed in the mid- and high-dose F_1 females in a rat reproduction study while no hormonal effect was observed in the F_1 male rats at any dose level. However, there were no corresponding changes in reproductive performance at any dose level. In the developmental toxicity study in rats, an increased incidence of wavy ribs was noted at the high-dose (1,000 milligrams/kilogram/day (mg/kg/day)), while an increased incidence of incompletely ossified sternal centra was observed at the mid- and high-dose levels. These incidences occurred in the presence of maternal toxicity. In the developmental toxicity study in rabbits, a downward flexion of the forepaws and/or hind paws was observed in the high-dose (1,000 mg/kg/day) group pups and delays in skeletal ossification were observed in pups at the mid- and high-doses. Maternal toxicity (adrenal effects) was also observed at the mid- and high- doses.

No evidence of neurotoxicity or immunotoxicity was observed in any of the submitted studies for cyflumetofen.

Although there is some evidence of thyroid tumors in rats, the Agency has determined that quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that

could result from exposure to cyflumetofen. This conclusion is based on the following reasons. The single tumor type (thyroid c-cell) occurred in only one sex (male) and one species (rat). This tumor effect was seen only at high doses (250 mg/kg/day), which far exceeds the chronic no-observed-adverse-effect-level (NOAEL) the Agency is using for its risk assessment (16.5 mg/kg/day). And there is no concern for mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by cyflumetofen as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Cyflumetofen: New Active Ingredient Human Health Risk Assessment to Support Uses on Citrus (Crop Group 10-10), Pome Fruits Crop Group 11-10), Tree Nuts (Crop Group 14-12), Grape, Strawberry, and Tomato" section IV, pg. 12 in docket ID number EPA-HQ-OPP-2012-0269.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a RfD - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some

degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for Cyflumetofen used for human risk assessment is shown in the following Table 1 of this unit.

Table 1.— Summary of Toxicological Doses and Endpoints for Cyflumetofen for Use in FFDCA Human Health Risk Assessment

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All populations)	An acute reference dose has not been established for either the general population or for Females 13-49 years of age since there were no appropriate studies that demonstrated evidence of toxicity attributable to a single dose for these populations			

Chronic Dietary (All Populations)	NOAEL = 16.5 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x	Chronic RfD = 0.17 mg/kg/day cPAD = 0.17 mg/kg/day	***Three co-critical studies*:** <u>90-day feeding study in rats:</u> LOAEL = 54.5/62.8 mg/kg/day (M/F) based on hematology and organ weight changes in the liver, adrenal, kidney and ovaries; and histopathology effects in the adrenals and the ovaries. NOAEL=16.5/19 mg/kg/day (M/F) <u>Chronic toxicity/carcinogenicity study in rats:</u> LOAEL = 49.5/61.9 mg/kg/day in (M/F) based on increased adrenal weights and histopathology. NOAEL=16.5/20.3 mg/kg/day (M/F) <u>Two generation reproduction study in rats:</u> Parental: LOAEL = 30.6/46.6 mg/kg/day (M/F) based on increased organ weight and histopathology in adrenals. NOAEL=9.2/13.8 mg/kg/day (M/F)
Inhalation (Short-, Intermediate- and Long-Term)	NOAEL = 16.5 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x	LOC for MOE = 100	Same as chronic dietary endpoint
Cancer (oral, dermal, inhalation)	The quantification of risk using a non-linear approach (*i.e.,* cRfD) will adequately account for all chronic toxicity, including carcinogenicity			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD

= population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to cyflumetofen, EPA considered exposure under the petitioned-for tolerances in 40 CFR 180. EPA assessed dietary exposures from cyflumetofen in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for cyflumetofen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The partially refined chronic analysis conducted was based on tolerance-level residues, 100% percent crop treated (PCT) assumptions, and both empirically derived and default processing factors.

iii. *Cancer*. Based on the data summarized in Unit III.A., the Agency has determined that quantification of risk using a nonlinear approach (i.e., RfD) would adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to cyflumetofen. Therefore, a separate cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyflumetofen. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cyflumetofen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyflumetofen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Ground Water Model as well as Pesticide Root Zone Model-Groundwater, the estimated drinking water concentrations (EDWCs) of cyflumetofen for chronic exposure assessments are estimated to be 0.33 parts per billion (ppb) for surface water and 0.0024 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.33 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). EPA assessed residential exposure using the following assumptions: The use of cyflumetofen on ornamentals in residential landscapes may result in residential handler exposure.

Residential handler exposure is expected to be short-term in duration as intermediate- or long-term exposures are not likely because of the intermittent nature of applications by homeowners. The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios:

- Mixing/loading/applying liquid to ornamentals with hose-end sprayer.
- Mixing/loading/applying liquid to ornamentals with manually-pressurized handwand.
- Mixing/loading/applying liquid to ornamentals with backpack.
- Mixing/loading/applying liquid to ornamentals with a sprinkler can.

Since no dermal hazard was identified for cyflumetofen in the toxicological database, only inhalation exposure assessments were conducted for residential handlers. EPA did not assess post-application exposure from the use of cyflumetofen in residential settings because:

1. No dermal hazard was identified in the toxicity database for cyflumetofen, so a quantitative residential post-application dermal risk assessment is not required;

2. Post-application inhalation exposure while performing activities in previously treated gardens was not assessed due to the low vapor pressure and the expected dilution in outdoor air after an application has occurred;

3. The potential for post-application non-dietary ingestion exposure for children ($1 < 2$ years old) is greatly diminished since young children are not expected to engage in the types of activities associated with these areas (e.g., gardening) or utilize these areas for prolonged periods of play.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found cyflumetofen to share a common mechanism of toxicity with any other substances, and cyflumetofen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyflumetofen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA

either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. There is no evidence of increased qualitative or quantitative susceptibility in the rat 2-generation reproduction study; however, the rat and rabbit developmental studies indicate susceptibility in the pups. There is evidence of increased quantitative susceptibility in the rabbit developmental toxicity study, since developmental effects (changes in ossification, paw flexion, and decreased fetal body weights) at the limit dose were observed where no maternal toxicity was present. There is evidence of increased qualitative susceptibility in the rat developmental toxicity study as developmental effects (increased incidence of incompletely ossified sternal centra) were seen at the same dose that caused an increase in adrenal weights and organ-to-body weight ratio in the maternal animals. Notwithstanding, the degree of concern for these effects in infants and children is low because the rat and rabbit developmental effects have clearly defined NOAEL/LOAELs and the dose selected for chronic risk assessment is protective of these effects. Therefore, the PODs based on adrenal effects in rat are health protective of all lifestages.

3. Conclusion. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cyflumetofen is complete.

ii. There is no indication that cyflumetofen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is some evidence that cyflumetofen results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. However, as described in Unit III.D.2., because of the low degree of concern for these effects, it is not necessary to retain the 10X FQPA factor to adequately protect infants and children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyflumetofen in drinking water. These assessments will not underestimate the exposure and risks posed by cyflumetofen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyflumetofen is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyflumetofen from food and water will utilize 2.3% of the cPAD for children 1-2 years old, the population group receiving

the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyflumetofen is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyflumetofen is currently proposed for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyflumetofen.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures are above the Level of Concern (LOC) of 100 and are not of concern (MOEs $\geq$ 100).

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, cyflumetofen is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population*. Based on the data summarized in Unit III.A., EPA has concluded that the cPAD is protective of potential cancer effects. Given the results of the chronic risk assessment, cyflumetofen is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyflumetofen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for cyflumetofen.

C. Revisions to Petitioned-For Tolerances

EPA revised the commodity names for the requested tolerances consistent with its policy to establish crop group tolerances using the most recently established crop groups. This policy was explained in the most recent rulemaking establishing crop groups in the

Federal Register on August 22, 2012 (77 FR 50617) (FRL-9354-3). Under this policy, rather than establish new tolerances under the pre-existing crop groups, EPA intends to conform petitions seeking tolerances for crop groups to the newer established crop groups, as part of its effort to eventually convert tolerances for any pre-existing crop group to tolerances with coverage under the revised crop group. Therefore, although the petitioner had requested tolerances on fruit, citrus, group 10; fruit, pome, group 11; and nut, tree, group 14. EPA evaluated and is establishing tolerances for fruit, citrus, group 10-10; fruit, pome, group 11-10; and nut, tree, group 14-12, respectively.

The petitioner requested a tolerance of 0.2 ppm for tomato based on residues found in tomatoes that had been frozen and stored in accordance with OECD Guideline 506 (October 16, 2007) to account for residue loss that may have occurred during storage. EPA is establishing a tolerance for tomato at 0.40 ppm. In addition, EPA is not establishing a separate tolerance for grape, raisin of 0.9 ppm, as requested, since the tolerance for the raw agricultural commodity grape at 0.60 ppm is adequate to account for any residue concentration shown in the processed commodity.

V. Conclusion

Therefore, tolerances are established for residues of cyflumetofen, in or on almond, hulls at 4.0 ppm; citrus, oil at 16 ppm; grape at 0.60 ppm; fruit, citrus, group 10-10 at 0.30 ppm; fruit, pome, group 11-10 at 0.30 ppm; nut, tree, group 14-12 at 0.01 ppm; strawberry at 0.60 ppm; and tomato at 0.40 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 9, 2014.

Jack Housenger,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.677 is added to subpart C to read as follows:

§ 180.677 Cyflumetofen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide cyflumetofen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels for cyflumetofen is to be determined by measuring only cyflumetofen, 2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate, in or on the commodity.

Commodity	Parts per million
Almond, hulls	4.0
Citrus, oil	16
Fruit, citrus, group 10-10	0.30
Fruit, pome, group 11-10	0.30
Grape	0.60
Nut, tree, group 14-12	0.01
Strawberry	0.60
Tomato	0.40

(b) *Section 18 emergency exemptions*. [Reserved]

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

[FR Doc. 2014-11496 Filed 05/20/2014 at 8:45 am; Publication Date: 05/21/2014]